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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/450,880 11/29/99 CRAIG

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| EXAMINER |
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HM12/0411

JOHN P WHITE  
COOPER & DUNHAM LLP  
1185 AVENUE OF THE AMERICAS  
NEW YORK NY 10036

|              |              |
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| HOUTTEMAN, S |              |
| ART UNIT     | PAPER NUMBER |

1656  
DATE MAILED:

04/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/450,880**

Applicant(s)  
**Craig**

Examiner  
**Scott Houtteman**

Group Art Unit  
**1656**



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-24 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-24 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for known 5-HT<sub>1F</sub> agonists and analogs with similar structures, does not reasonably provide enablement for the generic class of 5-HT<sub>1F</sub> agonists defined only by the desired property of specific activation of the 5-HT<sub>1F</sub> receptor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1-24 are broadly drawn to 5-HT<sub>1F</sub> agonists which specifically activate only the 5-HT<sub>1F</sub> receptor. These claims recite activation of 5-HT<sub>1F</sub> to various levels higher than other receptors, such as other 5-HT receptors, "adrenoceptors" and histamine receptors.

The specification, however, lacks guidance on how to make, de novo, any receptor agonists that would have these properties. The specification merely refers to previously isolated and tested agonists. See, for example specification page 17, lines 10-32. The molecular structure of these agonists are unpredictable. Given the core ring structure of an agonists, one could not predict any of the other core ring structures.

Furthermore, the prior art disclosures of agonists lack any general guidance that would direct one to systematically make a reasonable number of agonists having the claimed properties. See for example Flaugh et al., US Pat. 5,846,995, 12/1998. Flaugh et al. disclose agonists

without any guidance on how these particular structures were chosen. Flaugh et al. simply demonstrate that their agonists function by testing the agonists in various binding assays. See Flaugh et al. col. 42, Table II, for example. Thus, the state of the art in this field is that one can predict only the generally applicable organic chemistry rule that molecules having analagous structure will have similar properties. One cannot predict, using the ring structure of one class of agonists, the structure of a new, distinct class of agonists.

Due to the great breadth of the claims, the lack of guidance in the current specification and the unpredictability of finding new classes of agonists, it would require undue experimentation for the art skilled to enable a reasonable number of embodiments.

The art skilled would be forced to perform brute force trial and error of making arbitrarily chosen compounds and testing them in binding assays without any guidance on which compounds would function.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 1-24 are rejected under 35 U.S.C. 102(a) as being anticipated by Flaugh et al., US Pat. 5,846,995, 12/1998.

The treatment claims of the current case are broadly drawn to "administering" a "therapeutically effective amount" of an agonist. The agonist is not limited to any structure but

merely limited by recited characteristics of an agonist which specifically activates the 5-HT<sub>1F</sub> receptor rather than various other receptors.

These claims read on the Flaugh et al. treatment methods. Flaugh discloses "administering" therapeutically effective amounts of a 5-HT<sub>1F</sub> agonists col. 2, lines 28-33, col. 29, lines 40-52.

Note that while the claims preamble recites "treating urinary incontinence" there is no positive method step which limits the claim to avoid the Flaugh treatments. Thus, the claims cover both incontinence treatment and Flaugh's migraine headache treatment.

It is suggested that the claims be limited, for example by adding a step reciting "administering to a patient suffering from urinary incontinence." Support for any amendment (even those suggested by Examiners) must be pointed out in the original disclosure.

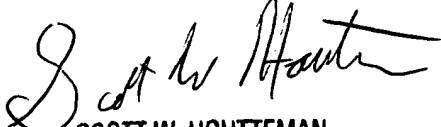
4. Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Technology Center 1600 Fax numbers are (703) 305-3014 and 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott Houtteman whose telephone number is (703) 308-3885. The examiner can normally be reached on Tuesday-Friday from 8:30 AM - 5:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Scott Houtteman  
March 20, 2001

  
SCOTT W. HOUTTEMAN  
PRIMARY EXAMINER